

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, DIANA
ZALDONIS,

Plaintiffs,

v.

UNIVERSITY OF PITTSBURGH OF THE
COMMONWEALTH SYSTEM OF
HIGHER EDUCATION

Defendant.

2:19-CV-01220-CCW

OPINION

Before the Court is a Motion for Summary Judgment, ECF No. 84, filed by Defendant the University of Pittsburgh (“the University”). For the following reasons, the Motion will be GRANTED.

I. BACKGROUND

A. Procedural History

On September 24, 2019, Diana Zaldonis filed a sealed *qui tam* complaint pursuant to 31 U.S.C. § 3730(b) of the False Claims Act (“FCA”). The Court unsealed the complaint after the United States declined to intervene. ECF Nos. 5 & 6. On May 14, 2021, the Court dismissed Ms. Zaldonis’ FCA claims against former Defendants University of Pittsburgh Physicians (“UPP”) and University of Pittsburgh Medical Center (“UPMC”) pursuant to 31 U.S.C. § 3729(a)(1)(A)–(B) (Counts I and II) with leave to amend. ECF No. 42. Ms. Zaldonis did not file an amended complaint within the time provided, so the Court dismissed these claims with prejudice and dismissed UPP and UPMC from the case. ECF Nos. 43, 50.

The only remaining claims in the case are a retaliation claim pursuant to § 3730(h) of the FCA (Count III) and a wrongful termination claim under Pennsylvania law (Count IV), both brought against the University of Pittsburgh. The University has moved for summary judgment on both claims, and that Motion is now fully briefed and ripe for disposition. ECF No. 84.

B. Material Facts

The following facts are undisputed unless otherwise noted. Ms. Zaldonis worked at-will as a Clinical Research Coordinator for the University. ECF No. 85 ¶¶ 1; ECF No. 85-2 at 14:2–7; ECF No. 88 ¶ 1. She has worked in clinical research since 1982—almost four years of that time she worked for UPMC and almost twenty years for the University. ECF No. 85 ¶¶ 1–2; ECF No. 85-2 at 13:8–15, 14:2–7. As part of her job, she assisted with two clinical trials, the XVIVO Clinical Trial and the Lung Bioengineering Clinical Trial, that were conducted out of UPMC. ECF No. 85 ¶¶ 11, 13. The XVIVO Clinical Trial was monitored by a third-party company, CRA Solutions. *Id.* ¶¶ 13–15.

The Clinical Research Coordinator has a certain degree of control over the data collection for a clinical trial, but the parties dispute how much this control amounted to. *See id.* ¶¶ 21–22. *But see* ECF No. 88 ¶¶ 21–22, 133 (noting the Clinical Research Coordinator “does not bear sole or ultimate responsibility for the data’s integrity”). The Clinical Research Coordinator did have access to patient consent forms. ECF No. 88-2 at 96:9–25.

For all clinical trials, an Institutional Review Board (“IRB”) acts as an independent reviewer and monitors the trials. ECF No. 85 ¶ 26; ECF No. 86 at 3. Federal regulations require each IRB to register with the U.S. Food and Drug Administration and to keep extensive reports about the clinical trials that must be made available for any federal inspection. ECF No. 87 at 15 (citing 21 C.F.R. §§ 56.106, 56.115).

Ms. Zaldonis worked with Dr. Pablo Sanchez, who was the director of the XVIVO Clinical Trial. ECF No. 85 ¶¶ 43, 50; ECF No. 88 ¶ 50. Ms. Zaldonis alleges that in September of 2018, Dr. Sanchez informed her that a patient was filing a medical malpractice suit against him, and he needed the patient's informed consent form. ECF No. 88 ¶ 152. Upon locating the form, Ms. Zaldonis discovered that Dr. Sanchez had not signed the consent form as the treating physician. *Id.* ¶ 153. According to Ms. Zaldonis, Dr. Sanchez asked her if she would report this violation to the IRB, and she responded that she had to. *Id.* ¶ 154. The parties dispute whether this conversation occurred. ECF No. 93 at 3–4.

Ms. Zaldonis then reported the deviation in the informed consent protocol to an online portal and later received an email notification that it had been submitted to the IRB. ECF No. 88 ¶¶ 4, 156; ECF 87 at 4. Ms. Zaldonis states that she reported the deviation because she believed that UPMC and the University submitted a claim falsely certifying compliance with the regulations for the U.S. Centers for Medicare & Medicaid Services (“CMS”). ECF No. 87 at 14.

Ms. Zaldonis alleges that after her conversation with Dr. Sanchez, he initiated a campaign to have her terminated. ECF No. 88 ¶¶ 157; ECF No. 87 at 6–10. The University disputes this characterization but agrees that in October of 2018, Dr. Sanchez informed Ms. Zaldonis' supervisor that he had issues with her performance. ECF No. 85 ¶ 64. Afterwards, Human Resources began an investigation and ultimately recommended that she be terminated. *Id.* ¶¶ 70, 72, 86–89. Ms. Zaldonis was terminated on January 8, 2019. *Id.* ¶ 97; ECF No. 88 ¶ 206.

There is significant dispute regarding Ms. Zaldonis' job performance. The University has stated that she was unprofessional in her communication style, ECF No. 85 ¶¶ 32–33, 35–36, 38–39, 44–46, that she was difficult to work with, *id.* ¶¶ 37, 51–52, and that she shared information between two clinical trials that could jeopardize the studies, *id.* ¶¶ 25, 53, 61–63.

Ms. Zaldonis largely disputes claims about her poor performance. ECF No. 88 ¶¶ 32–36, 37, 38–39, 44–46, 53, 61–63, 182–83, 205. She states that she received positive evaluations from her supervisors, *id.* ¶¶ 135–139, and had never received any formal disciplinary action beyond a single warning from years ago, *id.* ¶¶ 140–41.

II. LEGAL STANDARD

“The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). “Summary judgment is appropriate when the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.” *Mann v. Palmerton Area Sch. Dist.*, 872 F.3d 165, 170 (3d Cir. 2017) (internal citations and quotation marks omitted). “A factual dispute is ‘genuine’ if the ‘evidence is such that a reasonable jury could return a verdict for the nonmoving party.’” *Razak v. Uber Techs., Inc.*, 951 F.3d 137, 144 (3d Cir. 2020) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, (1986)). “A factual dispute is ‘material’ if it ‘might affect the outcome of the suit under the governing law.’” *Id.* (quoting *Anderson*, 477 U.S. at 248).

The burden to establish that there is no genuine dispute as to any material fact “remains with ‘the moving party regardless of which party would have the burden of persuasion at trial.’” *Aman v. Cort Furniture Rental Corp.*, 85 F.3d 1074, 1080 (3d Cir. 1996) (quoting *Chipollini v. Spencer Gifts, Inc.*, 814 F.2d 893, 896 (3d Cir. 1987)). That said, “[i]f the non-moving party bears the burden of persuasion at trial, ‘the moving party may meet its burden on summary judgment by showing that the nonmoving party’s evidence is insufficient to carry that burden.’” *Kaucher v. County of Bucks*, 455 F.3d 418, 423 (3d Cir. 2006) (quoting *Wetzel v. Tucker*, 139 F.3d 380, 383 n.2 (3d Cir. 1998)).

Once the moving party has carried its initial burden, the party opposing summary judgment “must do more than simply show that there is some metaphysical doubt as to the material facts Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no ‘genuine issue for trial.’” *Matsushita Elec. Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986). Thus, while “[t]he evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor,” *Anderson*, 477 U.S. at 255, summary judgment “requires the nonmoving party to go beyond the pleadings” and point to “‘specific facts showing that there is a genuine issue for trial,’” *Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986) (quoting Fed. R. Civ. P. 56(e)). But, while the court must “view the facts in the light most favorable to the non-moving party and draw all reasonable inferences in that party’s favor . . . to prevail on a motion for summary judgment, the non-moving party must present more than a mere scintilla of evidence; there must be evidence on which the jury could reasonably find for the [non-movant].” *Burton v. Teleflex Inc.*, 707 F.3d 417, 425 (3d Cir. 2013) (cleaned up). If the non-moving party “fails to make a showing sufficient to establish the existence of an element essential to [the non-movant’s] case, and on which [the non-movant] will bear the burden of proof at trial,” Rule 56 requires the entry of summary judgment because such a failure “necessarily renders all other facts immaterial.” *Celotex*, 477 U.S. at 322–23; *Jakimas v. Hoffman La Roche, Inc.*, 485 F.3d 770, 777 (3d Cir. 2007).

III. DISCUSSION

A. Retaliation Under the False Claims Act

The FCA prohibits a person from knowingly making a false or fraudulent claim for the purpose of receiving federal funding. 31 U.S.C. § 3729(a). Under the FCA, private parties—referred to as relators—can file a *qui tam* action against someone believed to be making such

claims. *Id.* § 3730(b). To protect relators, Congress enacted a provision prohibiting retaliation against them because of lawful actions they take to report potential violations of the FCA. *See id.* § 3730(h).

The FCA retaliation provision provides that:

Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent or associated others in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter.

31 U.S.C.S. § 3730(h)(1).

To make out a prima facie case of retaliation under the FCA, the party bringing suit must show that she (1) engaged in protected conduct that was in furtherance of a viable claim under the FCA; and (2) experienced discrimination because of the protected conduct. *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 186 (3d Cir. 2001); *Dookeran v. Mercy Hosp. of Pittsburgh*, 281 F.3d 105, 108 (3d Cir. 2002). An employer discriminates “because of” the protected conduct only when the plaintiff demonstrates that the employer had knowledge of the plaintiff’s participation in the protected conduct and but-for plaintiff’s participation, the adverse action would not have occurred. *Hutchins*, 253 F.3d at 186; *DiFiore v. CSL Behring, LLC*, 879 F.3d 71, 76–78 (3d Cir. 2018). Once a prima facie case is met, “the burden shifts to the employer to prove the employee would have been terminated even if [s]he had not engaged in the protected conduct.” *Hutchins*, 253 F.3d at 186.

Here, the parties dispute the first element—whether Ms. Zaldonis engaged in protected conduct. Ms. Zaldonis maintains that she engaged in protected conduct when she reported Dr. Sanchez’s protocol deviation to the IRB. ECF No. 87 at 14–15. According to Ms. Zaldonis, she

believed that the hospital submitted a claim that falsely certified compliance with CMS regulations. *Id.* at 14; ECF No. 88 ¶ 147. As support, Ms. Zaldonis has included the relevant regulations that require hospitals to obtain informed consent to receive federal funding. *Id.* at 14–15; ECF No. 1 ¶¶ 36–46 (citing 38 C.F.R. § 17.32; 42 C.F.R. §§ 482.51(b)(2), 482.24(c)(4)(v); 21 C.F.R. §§ 50.20; and 49 Pa. Code § 16.95(a)). The University argues that Ms. Zaldonis did not engage in protected conduct given that the report to the IRB would not have resulted in a viable FCA action. ECF No. 86 at 12–14.

A plaintiff engages in “protected conduct” when his or her actions are in furtherance of a viable claim under the FCA. *Dookeran*, 281 F.3d at 108. Viability, however, does not require that a plaintiff produce a winning claim. *See Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 545 U.S. 409, 416 n.1 (2005) (“[P]roving a violation of [the FCA] is not an element of [the retaliation] cause of action.”); *United States ex rel. Petras v. Simparel, Inc.*, 857 F.3d 497, 508 (3d Cir. 2017). That said, “an employee’s investigation of nothing more than [her] employer’s non-compliance with federal or state regulations” cannot form the basis of a viable claim under the FCA. *Hutchins*, 253 F.3d 176, 187–88 (quoting *United States ex rel. Yesudian v. Howard Univ.*, 153 F.3d 731, 740 (D.C. Cir. 1998)); *Campion v. Ne. Utils.*, 598 F. Supp. 2d 638, 657 (M.D. Pa. 2009).

The purported “protected conduct” in this case is a report about regulatory violations. Ms. Zaldonis states that she reported the deviation in the informed consent protocol because she “had reason to believe that [a patient’s] claim falsely certified compliance with CMS regulations.” ECF No. 87 at 14. Because the report at issue accused the hospital of nothing more than a failure to comply with CMS regulations, she did not engage in protected conduct in furtherance of the FCA.

Because Ms. Zaldonis has not satisfied the first element of her prima facie case, we need not address the second element of the prima facie case or engage in the burden-shifting analysis on whether she would have been terminated but for the report to the IRB. Accordingly, Ms. Zaldonis' retaliation claim pursuant to 18 U.S.C. § 3730(h) (Count III) must be dismissed.

B. Wrongful Termination Under Pennsylvania Law

Ms. Zaldonis' only remaining claim (Count IV) is for wrongful termination under Pennsylvania common law. An at-will employee like Ms. Zaldonis generally cannot pursue a wrongful termination in Pennsylvania. *McLaughlin v. Gastrointestinal Specialists, Inc.*, 750 A.2d 283, 287 (Pa. 2000); *Shick v. Shirey*, 716 A.2d 1231, 1233 (Pa. 1998) (“[A]s a general rule, no cause of action exists based upon an employer’s termination of an at-will employment relationship.”). There is, however, an exception “where the termination [of an at-will employee] implicates a clear mandate of public policy.” *McLaughlin*, 750 A.2d at 287. The limited scenarios where courts have recognized such a wrongful termination claim are when an employee is discharged after (1) refusing to commit a crime; (2) complying with a statutorily imposed duty; or (3) exercising a constitutional right. *Fraser v. Nationwide Mut. Ins. Co.*, 352 F.3d 107, 112 (3d Cir. 2003); *Hunter v. Port Auth. of Allegheny Cnty.*, 419 A.2d 631, 638 (Pa. Super. 1980). Ms. Zaldonis argues that she was discharged for her refusal to commit a crime and for complying with a statutorily imposed duty. ECF No. 87 at 19.

Establishing a wrongful termination claim based on a party’s refusal to commit a crime is a high hurdle, but has been recognized in circumstances where an employer asked the employee to commit an illegal act that would subject them to criminal liability. *See, e.g., Woodson v. AMF Leisureland Ctrs., Inc.*, 842 F.2d 699, 702 (3d Cir. 1988) (demanding a bartender serve alcohol to intoxicated individuals in violation of Pennsylvania law); *Dugan v. Bell Tele. of Pa.*, 876 F. Supp. 713, 725 (W.D. Pa. 1994) (requiring an employee destroy subpoenaed records that could have

exposed him to criminal liability). Ms. Zaldonis argues that had she not reported Dr. Sanchez's deviation from the informed consent protocols, she would have committed a crime. Specifically, she argues that a failure to report would expose her to liability under 49 Pa. Code § 16.95, which provides, "A physician shall maintain medical records for patients which accurately, legibly and completely reflect the evaluation and treatment of the patient." 49 Pa. Code § 16.95(a). Importantly, this statute specifies that the *physician* must maintain accurate medical records for patients. In fact, obtaining informed consent "is a non-delegable duty owed by the physician," such that other parties cannot be liable for a physician's failure to obtain informed consent. *See Shinal v. Toms*, 162 A.3d 429, 453 (Pa. 2017); *see also Foflygen v. Zemel*, 615 A.2d 1345, 1353 (Pa. Super. 1992) (declining to hold a nurse liable for the failure to obtain informed consent). Indeed, Ms. Zaldonis concedes that "[o]btaining a patient's informed consent was the sole and exclusive responsibility of the treating physician." ECF No. 88 ¶ 145. Therefore, she faced no criminal liability for an already executed informed consent form over which Dr. Sanchez, as the treating physician, had sole responsibility. Accordingly, her argument that she would have committed a crime had she not reported the lack of informed consent is unpersuasive.

Ms. Zaldonis next argues that she had a statutorily imposed duty to report violations to the IRB pursuant to 49 Pa. Code § 21.18(b)(1), which prohibits a registered nurse from knowingly aiding, abetting, or assisting another person from violating or circumventing a law or Board regulation. ECF No. 87 at 19. In Pennsylvania, a statutorily imposed duty must be an act that a person is required by law to perform. *See, e.g., Field v. Phila. Elec. Co.*, 565 A.2d 1170, 1180 (1989) (a health physics technician who was required to report safety violations to the Nuclear Regulatory Commission); *Reuther v. Fowler & Williams*, 386 A.2d 119, 121 (Pa. Super. 1978) (a person reporting for jury duty). The statute must have an affirmative mandate to act. *Hennessy v.*

Santiago, 708 A.2d 1269, 1273–74 (Pa. Super. 1998); *Brennan v. Cephalon, Inc.*, 298 Fed App’x 147, 151 (3d Cir. 2008); *Kent v. Keystone Hum. Servs.*, 68 F. Supp. 3d 565, 570 (M.D. Pa. 2014). This affirmative mandate requirement extends to the healthcare context, and courts have dismissed cases when a statute did not explicitly impose a reporting obligation on the medical professional to report the violation. *Spierling v. First Am. Home Health Servs.*, 737 A.2d 1250, 1254 (Pa. Super. 1999); *Kent*, 68 F. Supp. 3d at 570; *Diberardinis-Mason v. Super Fresh*, 94 F. Supp. 2d 626, 629–30 (E.D. Pa. 2000).

Here, Ms. Zaldonis argues that she acted pursuant to the Pennsylvania Standards of Nursing Conduct, which are set forth in 49 Pa. Code § 21.18(b)(1). ECF No. 87 at 19–20. This statute, however, does not have an affirmative duty for a nurse to report violations of informed consent. Rather, it simply mandates that a nurse may not “knowingly aid, abet or assist another person” in violating or circumventing a law or Board regulations. Given that this affirmative duty to report must be explicit, Ms. Zaldonis has not met this requirement. *See, e.g., Spierling*, 737 A.2d at 1254 (dismissing a nurse’s wrongful termination claim because the statutes related to a registered nurses’ conduct do not include a mandatory reporting provision). Accordingly, because Ms. Zaldonis fails to meet one of the narrow public policy exceptions, the University is entitled to summary judgment on this claim.

IV. Conclusion

For the foregoing reasons, the University's Motion for Summary Judgment, ECF No. 84, will be GRANTED as set forth in the accompanying ORDER.

DATED this 26th day of October, 2022.

BY THE COURT:

/s/ Christy Criswell Wiegand
CHRISTY CRISWELL WIEGAND
United States District Judge

cc (via ECF email notification):

All Counsel of Record